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## **Unna boot compared to elastic bandages in patients with venous ulcers: clinical trial**

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### **ABSTRACT**

The main cause of venous ulcers is the venous hypertension and resulting capillar hypertension. The treatment aim is to reverse venous hypertension to the superficial veins level of lower members, and this is why compression therapy is indicated for these patients. **Objective:** Describe the process of tissue repair in venous ulcer patients using inelastic compression therapy (Unna Boot) compared to elastic bandages. Compare the clinical and evolving results of the tissue repair process of venous ulcers in patients submitted to treatment with inelastic and elastic therapy. **Method:** This is an experimental, randomized, controlled, open and prospective clinical trial, with quantitative approach, held in a University Hospital. The sample will be of 18 patients, accompanied during 13 weeks. The instrument of data collection will have socio-demographic, clinical and specific questions about the ulcer. The data analysis will be on SPSS software as basis.

**Descriptors:** Unna Boot; compression therapy; venous ulcer.

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## **SITUATION/PROBLEM AND ITS SIGNIFICANCE**

The main cause of venous ulcers is the venous hypertension and resulting capillary hypertension <sup>(1,2)</sup>. The treatment aim is to reverse venous hypertension to the superficial veins level of lower members, and this is why compression therapy is indicated for these patients <sup>(2,3)</sup>. Nowadays, there's a great variety of compression therapies in the market for venous ulcers treatment, but it's not still clear if they're all really effective or which one of these therapies has the best indication <sup>(2)</sup>. The objectives of the trial are: Evaluation of clinical and evolving results of the tissue repair process of patients with venous ulcers that are submitted to inelastic compression therapy (Unna Boot) compared to elastic therapy (elastic bandage); examine satisfaction and comfort of the patient during both compression therapies.

## **METHODOLOGY**

This is an experimental, randomized, controlled, open and prospective clinical trial, with quantitative approach. It will be developed at Antonio Pedro University Hospital Outpatient Wounds Repair. The sample will be of 18 patients. For random allocation, a list will be done on Biostat 5.0 software that will have a draw to split the participants in two groups, one group will use Unna Boot as treatment, and the other will use elastic bandage, this one will use vaseline gauze as primary bandage. The list will be applied to the participants before entering the trial. All the volunteers must follow some requirements of inclusion: adult patients, both genres, diagnosed with venous ulcer, with ankle-brachial index higher than 0,9. Excluded from trial: Bedridden patients and/or wheelchair users; diabetics; patients diagnosed with arterial, neuropathic or mixed ulcer; those who suffer from allergy to any product used in the trial; infection in ulcer bed; pain and cyanosis on lower limb after application of the product; in use of corticoids. Monitoring time will be of 13 weeks. The project was approved by the Ethics Committee in Research of the Faculty of Medicine, University Hospital Antonio Pedro, under protocol nº 327/2010 and CAAE:0252.0.258-000-10, suiting Resolution nº 196/96 of Ministry of Health that regulates criteria for research using human beings. It's

properly registered under denomination Trial (req:195) and WHO UTN U1111-1122-5489 at Brazilian Clinical Trials Registry.

Data collection will follow two stages. **Stage I:** Initial approach with every patient of each group, research information provision and signing of Informed Consent Form. One day later, elaboration of anamnesis and beginning of inelastic therapy usage (Unna Boot) or elastic therapy. **Stage II:** Weekly check-ups, with bandage changings, injuries clinical evaluation, measurement, decal and digital photography through application of trial protocols. All the patients will be oriented to change the secondary bandage at home regularly, according to the exudate production of the ulcer, in addition of the bandage protection during the bath. These are the ways to prevent the ulcer odor and infection. The data analysis will be through descriptive and inferential statistics with basis on SPSS software, version 14.0 Windows.

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**Brazilian Clinical Trials Registry:** (req:195) e WHO UTN U1111-1122-5489.

## **PROJECT DATA**

**Project data:** Dissertation project for Academic Master's Health Care Sciences, of Aurora de Afonso Costa Nursing School, Fluminense Federal University. Approved at CEP: Medicine Faculty and Antonio Pedro University Hospital, Protocol 327/10, CAAE: 0252.0.258.000-10.

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